

Claims

What is claimed is:

- 5 1. A substrate coating for the electrostatic deposition of dry powder medicaments for use in the manufacture of pharmaceutical dosage forms comprising micronized polyethylene glycol (PEG), with molecular weight in the range of 1,000 to 20,000, and having a particle size of 1- 100  $\mu$ m..
- 10 2. The substrate coating of claim 1 having a melting point in the range of 50 - 63°C.
- 15 3. The substrate coating of claim 1 wherein the PEG has a molecular weight in the range of 6,000 - 8,000.
4. The substrate coating of claim 1 also containing a plasticizer.
- 20 5. The substrate coating of claim 4 wherein the plasticizer is selected from castor oil, polyethylene glycol, propylene glycol or glycerine.
- 25 6. The substrate coating of claim 1 also containing one or more coloring, pacifying, flavoring and/or sweetening agents.

7. A pharmaceutical composition comprising an edible substrate having micronized drug substance with a particle size of 1 - 100  $\mu\text{m}$  deposited on the surface of the substrate by electrostatic dry powder deposition, and a film coating on the substrate and drug substance consisting essentially of micronized polyethylene glycol (PEG), with molecular weight in the range of 1,000 to 20,000, and having a particle size of 1- 100  $\mu\text{m}$ .

8. The pharmaceutical composition of claim 7 wherein the film coating has a melting point in the range of 50 - 63°C.

9. The pharmaceutical composition of claim 7 wherein the PEG has a molecular weight in the range of 6,000 - 8,000.

10. The pharmaceutical composition of claim 7 wherein the PEG film coating (dried) constitutes from about 1 to about 10, percent by weight of the total weight of the solid dosage form.

11. The pharmaceutical composition of claim 7 wherein the edible substrate is comprised of a tablet core.

12. The pharmaceutical composition of claim 8 wherein the tablet core is prepared by compressing a mixture of microcrystalline cellulose (99 - 99.5%) and magnesium stearate (0.5 - 1%).

13. The pharmaceutical composition of claim 7 wherein the drug substance is selected from one or more estrogens and/or progestins.

14. The pharmaceutical composition of claim 13 wherein the drug substance is a combination of norgestimate and ethinyl estradiol.

5 15. In a process for manufacturing pharmaceutical unit dosage forms by the electrostatic deposition of dry powder medicament to a substrate, the improvement comprising coating the substrate in place with dry  
10 micronized polyethylene glycol (PEG), melting the dry polyethylene glycol coating and allowing it to cool whereupon a protective coating is formed.

16. A method of depositing negatively charged dry powder  
15 medicament on a negatively charged substrate by an electrostatic dry powder deposition process, the method comprising reversing the charge of the medicament to a positive charge by mixing the negatively charged medicament with micronized  
20 polyethylene glycol (PEG), at the ratio of medicament to PEG of 1:1 to 1:60, and then depositing the mixture onto the negatively charged substrate.

25 17. The method according to claim 16 wherein the PEG has a molecular weight in the range of 1,000 to 20,000 and a particle size of 1-100  $\mu\text{m}$ .

30 18. The method according to claim 16 wherein the PEG has a melting point in the range of 50-63°C.

19. The method according to claim 16 wherein the PEG has a molecular weight in the range of 6,000 to 8,000.

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